

ANKLE FOOT ORTHOTICS OPTIMIZATION BY MEANS OF COMPOSITE REINFORCEMENT OF FREE-FORM STRUCTURES

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Abstract

Ankle-Foot-Orthoses (AFOs) are assistive devices prescribed for a number of physical and neurological disorders affecting the mobility of the lower limbs. Traditional AFO design is based on thermoforming polymer sheets around a plaster cast with a characteristic stiffness depending on the selected trim-line with the inherent design limitations. Additive Manufacturing has been explored as an alternative process; however it has proved to be inefficient cost-wise. This work explores the possibilities of generating modular AFO elements: calf, shank, and footplate with localized composite reinforcement that aids in the optimization of the device in terms of functionality, aesthetics, rigidity and cost.

1.Introduction

Ankle-foot orthoses (AFOs) are orthopedic devices usually prescribed to address a number of common walking impairments such as stroke, multiple sclerosis or cerebral palsy [1, 2]. Their main purpose is to compensate the malfunctioning of the neuromuscular system which manifests in an unhealthy gait pattern localized in the foot and ankle e.g. drop foot, weak ankle and other impairments. The term “orthoses” refers to medical devices applied externally in order to help patients to gradually acquire healthier gait patterns.

Different types of AFOs are normally prescribed for various impairments depending on the intensity, range of movements and patient complexion. Some typical designs include: leaf spring AFOs, hinged, with dorsal cover, etc. [1]. Traditionally, patient-specific AFOs are made by one of two methods: 1) thermoforming copolymer sheets of a prescribed thickness (normally 3-4mm) around a plaster-cast impression or 2) Prepeg carbon fiber sheet layup using a plaster cast base as a reference surface. The typical plastic AFO manufacturing process is shown on figure 1 [3].



Figure 1. Typical stages for PP AFO manufacturing. a) Cast rectification b) PP sheet placement c) Edge cutting d) Add-ons

Carbon-fiber based AFOs offer stiffer and lighter structures and are manufactured by laying up thin layers of carbon fiber on a rectified positive casts, with a predefined bonding agent (epoxy resin), and alternating their orientation until the desired thickness / stiffness is achieved.

Typical productivity for both types of AFO manufacturing processes (plastic and carbon fiber) depends on manual labour skills (Table 1). Observed average production rates for a single worker on a per-day basis are 1- 3 carbon fiber AFOs and 2-4 polymer vacuum formed AFOs [3]. Lead times for both types of AFOs can vary significantly; while for polymer-based AFOs it is typically 1 week, for carbon-fiber AFOs it will vary between 1 to 3 weeks until the final delivery. The main parameters dictating the AFOs performance are the material type, thickness, trim line (lateral carving) [3-5], localized reinforcement, and footplate properties [1] which are normally selected by personal preference of the orthotist.

Table 1. Cost and productivity target for AFOs [3]

Product cost	€170 - €220 each
Typical productivity	3-4 full AFOs per working day
Total lead time	Approx. 10 days to reach customer

2. Additive Manufacturing of AFOs

Given the artisanal manufacturing style of personalised AFOs, additive manufacturing has been identified as a natural method to produce automated highly personalized devices that fit every patient's specific requirements [3]. Work on additive manufacture of AFOs has focused on highlighting the freedom of design associated with additive technologies. Pallari et.al [4] demonstrated the design, manufacturing and optimization possibilities of an SLS-made AFO scanned from a preexisting Polypropylene device. Schrank et.al [6] analyzed the dimensional accuracy of passive dynamic ankle-foot orthotics made by SLS by manufacturing scaled-down versions of the device, while Mavroidis et. al. [7] presented an AFO customization process by manufacturing two samples with the sthereolithography process which showed similar properties to a conventional PP AFO. Muraru et.al. [8] presented a different approach by modeling the necessary mechanical properties for a finite element material definition of laser sintered AFO devices. Other related research is based in new design-freedom and customization capabilities of additive manufacturing from a pure-design perspective [6, 8, 9]. However none of the previous research has addressed the feasibility of AM as a dedicated method for AFO manufacturing particularly concerning two factors: economics and performance optimization.

2.1 The build-time and cost limitation of Additive manufacturing for AFOs

One problem not usually described in literature is the build time and cost required for producing a full size AFO in one piece by any of the AM technologies. Even for the most versatile of processes such as SLS, obtaining a high productivity compared to conventional technologies can be impractical. A number of build time estimations for AFOS have been calculated for different product volumes. A generic 3D AFO design (Figure 2) has been placed in two SLS machines and a second stage of optimization has been performed by minimizing the Z height and packing multiple components in a single build. Results are presented on Table 2.

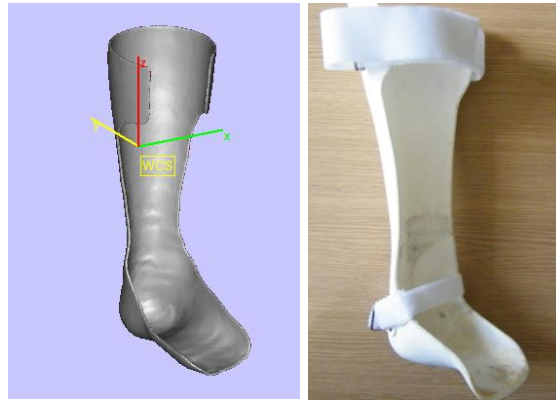
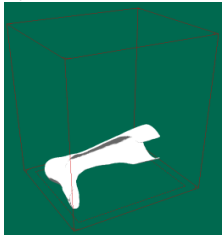


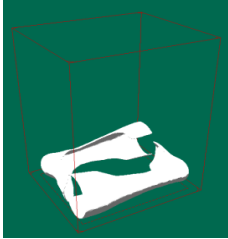


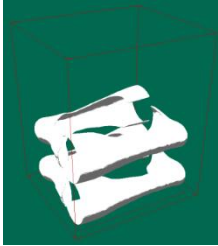







Figure 2. Generic AFO 3D STL file and SLS-made AFO Duraform PA

Table 2 Build time estimation for generic AFO design

Machine	Material	No. of parts	Powder base	Total build time	Warm-up Stage	Build Stages	Cool-down Stage
sPRO	DuraForm Polyamide Powder V3.45	1	5.70	08:52:35	01:34:53	06:21:42	00:56:00
SLS HiQ	DuraForm Polyamide Powder V3.45	1	5.60	09:18:53	01:34:53	06:22:46	01:21:14
  							
Machine	Material	No. of parts	Powder base	Total build time	Warm-up Stage	Build Stages	Cool-down Stage
sPRO	DuraForm Polyamide Powder V3.45	2	5.77	10:29:23	01:34:53	07:58:30	00:56:00
SLS HiQ	DuraForm Polyamide Powder V3.45	2	5.77	10:56:05	01:34:53	07:59:58	01:21:14
  							
Machine	Material	No. of parts	Powder base	Total build time	Warm-up Stage	Build Stages	Cool-down Stage
sPRO	DuraForm Polyamide Powder V3.45	4	10.69	18:18:07	01:34:53	15:47:14	00:56:00
SLS HiQ	DuraForm Polyamide Powder V3.45	4	10.69	18:45:07	01:34:53	15:49:00	01:21:14
  							
Machine	Material	No. of parts	Powder base	Total build time	Warm-up Stage	Build Stages	Cool-down Stage
sPRO	DuraForm Polyamide Powder V3.45	6	12.82	28:35:20	01:34:53	25:39:13	01:21:14
  							

Although build-time optimization can be pursued by making an efficient use of the build space the software-based build-time estimations suggested Ankle Foot Orthotics are not well suited for full size manufacture due to the high build time and costs involved, including material waste, machine preparation and generally lower productivity when compared to well established manufacturing methods. One approach for optimizing additive manufacture of AFO devices is the design of modular/independent elements which can be joined together by further secondary operations such as localized reinforcement with composite materials.

The use of composite materials such as carbon fiber/grass fiber- epoxy has been recurrent for automotive, aerospace and lightweight structures design and a number of cases make use of additive manufacturing structures as sacrificial structures used for the molding of composite materials [10, 11].

This research explores the use of additive manufacturing for the generation of modular/individual structures than can be joined into a single full-sized component by the use of localized composite reinforcement. For this study a low cost system (Bits from Bites-FDM) printing in PLA material was used for both: assessing the mechanical properties of localized reinforcement and obtaining a prototype orthotic device.

3 Method

3.1 Flexural tests specimen preparation

A total of 30 test specimens were prepared in compliance with [12] for a 3-point bending test in order to quantify the flexural properties of the PLA material along the 3 main build directions (X, Y & Z). Specimens were produced in a Bits from Bytes (low cost-FDM machine) and the build prepared using the Axon v2.0 software with the following parameters: layer thickness of 0.25mm, speed multiplier 1.3X, fill density 100%, fill pattern: linear. Specimens were packed in batches of 5 and the three groups were produced with a raft-base layer for further stability, which was fully removed prior to the tests.

Fifteen specimens (5 for each orientation) were tested in plain PLA material while the remaining 15 were subjected to a localized reinforcement by applying two layers of carbon-fiber/polyester fabric (East Coast Fiberglass, UK) with a combination of epoxy-hardener equivalent to a 5:2 mixing ratio respectively.

A preliminary layer of epoxy+ hardener agent was applied to the upper surface of the specimens and then after each successive carbon-fiber -layer. Specimens were left to cure for a period of 36 hours and then the excess hardened fiber was shaped to follow the original rectangular shape of the specimen.

3.2 Evaluation of mechanical properties of plain FDM specimens

The prepared specimens were tested in a Tinius Olsen H25KS universal testing machine with a 5k N load cell. The test setup showed on figure 3 followed the test procedure described by BS-EN-ISO 178:2003 with a cross sectional speed of 5mm/min and an automatic displacement limit of 50mm. The first set of experiments was performed on plain PLA specimens and then second batch on the reinforced specimens with the composite material facing downwards.

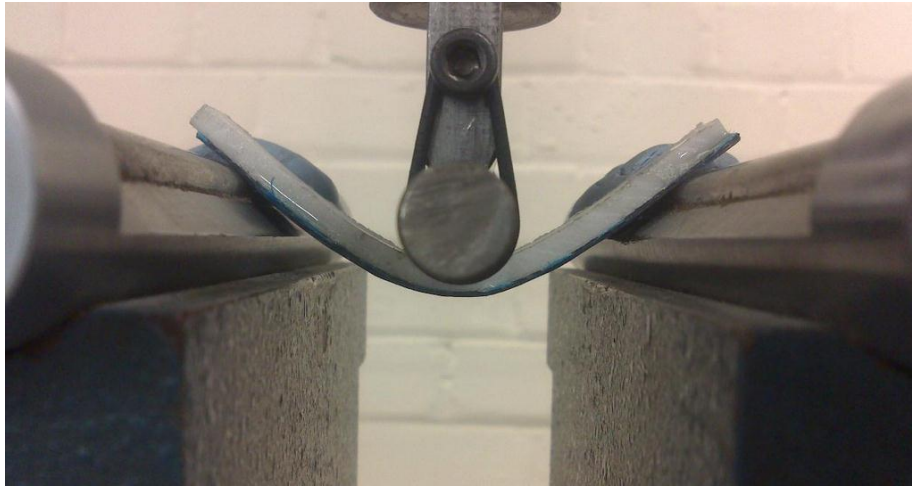


Figure 3. 3-point bending of PLA + reinforcement specimen

3.3 Design of modular complex shapes for an AFO

A prototype AFO device requested by a professional orthotists (Peacocks Medical Group, Newcastle, UK) was developed which is intended to measure the counter-force ejected by patients with hemiplegia. Some hemiplegic patients tend to develop a gait-deficit exhibited in the form of a knee hyperextension pattern while walking. Thus the proposed design would allow a full dorsiflexion movement while inducing a resistance to plantar flexion that is then recorded by a load cell placed at a given distance from the heel joint.

The prototype AFO device was designed in a modular way so that all elements fit the available build space on a BfB 3D touch machine. The full design was developed in Autodesk Inventor v13. and the file conversion/preparation was performed on the Axon v2.0 machine software. The effect of orientation was neglected as the full assembly was not intended to withstand loads during walking, but to act as a receptacle for localized reinforcements with a carbon fiber composite. The AFO elements requiring reinforcement were prepared on the relevant surface by removing all trace of support structures and leaving a plain smooth surface. A formulation of 5:2 Epoxy resin/hardener was applied to the base surface and two layers of carbon fiber sheet applied. The set of components was left to cure during a period of 36 hours at room temperature to allow for a complete cure cycle.

4 Results

4.1 Flexural tests results

The comparison of the flexural properties of plain PLA specimens against carbon-fiber reinforced under the 3-point test is shown on figures 4 and 5. The localized reinforcement with 2 layers of carbon-fiber and a 5:2 epoxy/hardener ratio provided an increase in flexural strength of 50% average, split along different orientation axis as follows: X=40%, Y=47%, and Z=71%.

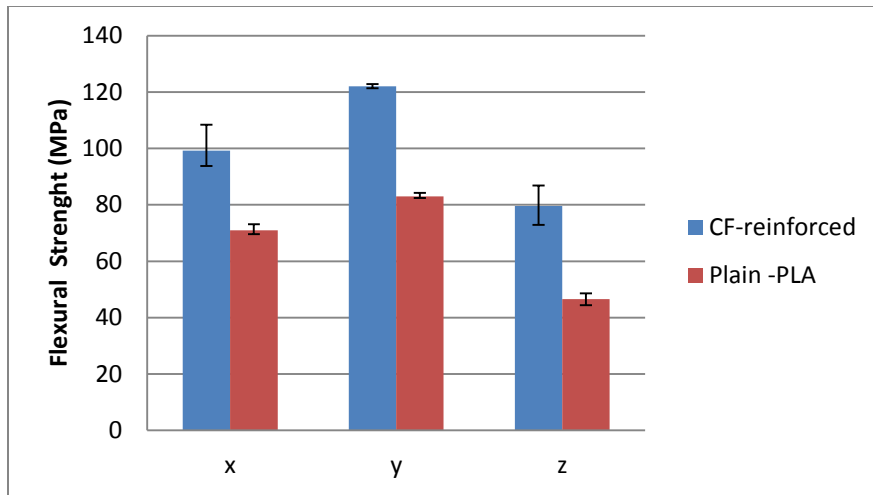


Figure 4. Flexural strength for both: plain- PLA and PLA + CF reinforcement along 3 build orientations

For the flexural modulus an increase of nearly 30% average was registered which was also consistent along the 3 main orientations: x=33%, y=22.6%, Z= 29% (figure 5).

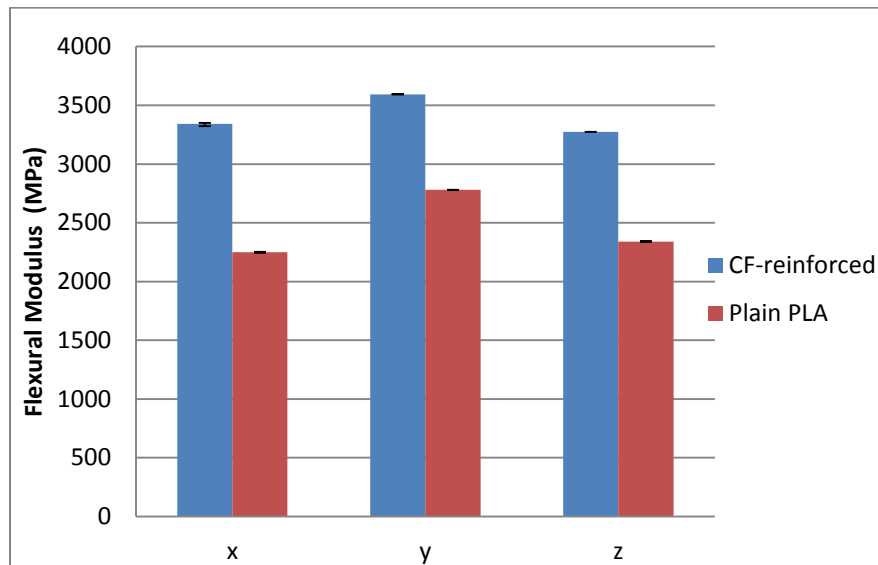


Figure 5 . Flexural strength for both: plain- PLA and PLA + CF reinforcement along 3 build orientations

Additionally the presence of a carbon-fiber reinforcement layer on the lower surface prevented the specimens from breaking during the test as they did when reinforcement is not applied. The major bending stresses concentrate on the lower face at the middle span as opposed to a conventional 3-point bending tests where compressive stress on the upper surface equals the tensile stress on the lower surface (figure 6).

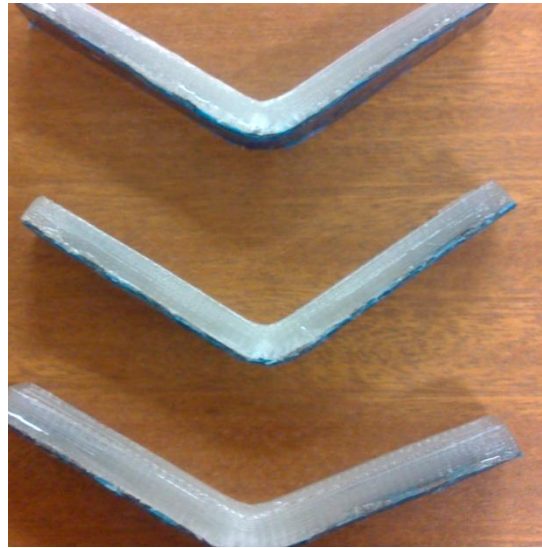


Figure 6- PLA specimens after test with a higher stress concentration area on the lower surface interfacing the carbon-fiber.

4.2 Design of modular complex shapes for an AFO

A prototype AFO device for the measurement of knee hyper extension forces was designed in Autodesk Inventor v13. Figure 7 shows the concept where various AFO parts were modeled separately and joined as an assembly so they can be placed individually in the build chamber of low cost FDM equipment (figure 8).

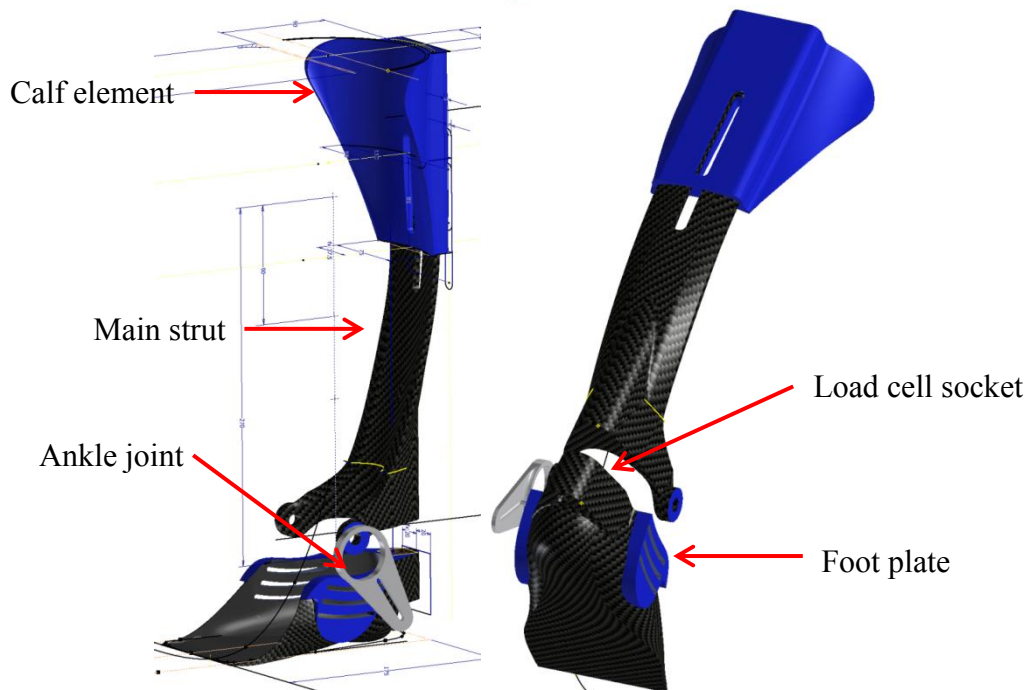


Figure 7. 3D CAD of AFO jig for in-lab stiffness measurement with footplate, calf and post section printed in PLA (Blue) and Carbon fiber reinforced

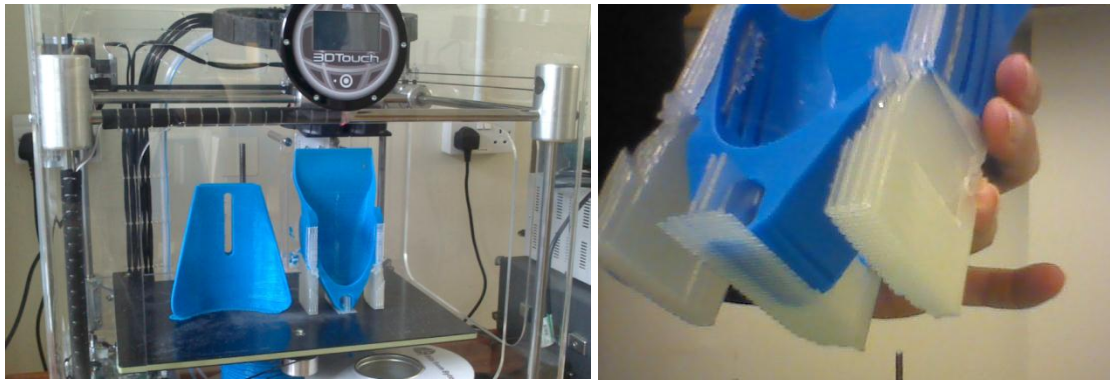


Figure 8. FDM fabrication of multiple components for FDM- carbon fiber reinforced AFO

The total build time for the separate elements was 16 hours, however various trials were tested where the full set of components could be embedded in one single build cycle below 12 hours, mainly by increasing the layer thickness parameters and deposition rate. The resulting parts in PLA material were individually reinforced by means of carbon fibre/Blue polyester (East Coast Fibre glass, UK) plus epoxy resin in order to provide extra rigidity in selected areas: foot plate/external surface, main strut/both sides. Results are shown in figure 9 where the final structures comprise a prototype stiffness measuring jig.



Figure 9. Final FDM-made AFO jig fabricated by multiple PLA components - carbon fiber reinforced (UNEW)

5 Discussion

5.1 Conventional vs Additive manufacturing of AFOs

Although ankle foot orthotics have been studied by previous research they remain a challenge for AM-based production due to the overall build-size and the time implications of building each device in one piece. The productivity of conventional methods still surpasses that of AM for both, SLS and FDM however the advantages of digital fabrication lay on the design opportunities when designing the final devices, as no plaster casts are required to mould the plastic.

A modular design approach has been introduced where the three main elements of an AFO: Calf, footplate and strut are split and arranged within the build envelope so the full set of components is produced in one single build and assembled afterwards.

Due to the need for support structures the FDM method is not the best technology for optimizing packing ratios as the rotation of individual components to minimize the z-height has a direct affect on the build time due to the need for support structures (figures 10 and 11).

Therefore the optimum orientation for FDM is when parts can be built without the need of support structures.

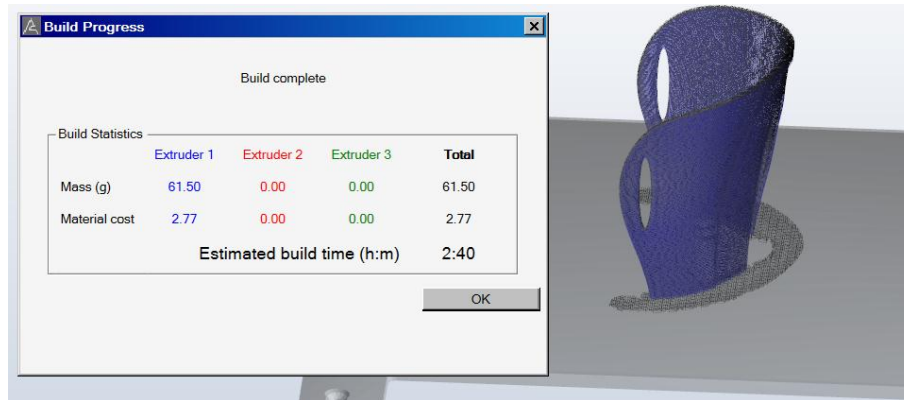


Figure 10. Build time for calf part built along the Z axis in Axon v2.0 software.

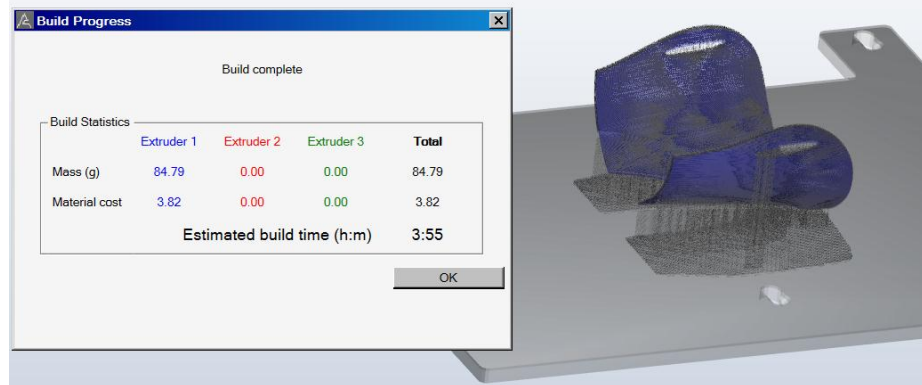


Figure 11. Build time for calf rotated 90 degree to minimize Z height via support structures.

5.2 Effect of localized reinforcement with composite material

The localized reinforcement of sacrificial structures has been studied in different fields from automotive applications [11] to complex tooling design [10] or art artifacts [13]. However the specific effect that a predetermined composite material formulation can provide to a structure made by additive manufacturing had not yet been reported.

As the results presented in this work suggest, a localized reinforcement of two layers of carbon fibre-polyester with a 5:2 epoxy-hardener ratio have an effect of nearly 50% increase in flexural strength and approximately 30% in flexural modulus across the 3 main build directions. However the most important characteristic is the structural stability the composite provides to strengthen the AM-made components preventing rupture even after the plastic section has failed.

Further work could address the effect of different epoxy/hardener ratios, the use of additional reinforcement layers or the localized reinforcement on both sides of the was out of the scope of this work this work suggests the use of low cost additive manufacturing parts as composite-deposition surfaces or guides can find applications in end-use products that do not necessarily need an oversized plastic structure but a lightweight-complex overall shape with good mechanical properties.

6. Conclusion

The use of low cost AM components in conjunction with composite materials can open new avenues for the design of high complexity products without the need for expensive tooling components or secondary operations such as plaster cast, wood mould machining or

thermoforming substrates. However, plastic components being used as a guide-surface or sacrificial skeleton must provide sufficient rigidity for the composite deposition stages, particularly when pressures will be applied by means of vacuum bagging, resin transfer moulding, or simply by applying uniform pressures manually.

The solution presented in this work for an orthotic device is based on thin walled components printed along the Z axis without the need of support structures. It has been observed that adhesion of PLA to CF-polyester composites is sufficient for prototyping purposes however additional tests must be performed according to the final purpose of the device, e.g. epoxy resin penetration range vs. wall thickness, tensile tests of hollow vs dense polymer substrates, etc.

This work introduces the low-cost 3D printing plus reinforcement approach as an alternative route for the design and manufacture of orthotic devices with complex shapes and localized reinforcement needs. It is expected that new applications add-up to increase the body of knowledge about the behaviour of such products which will mix both areas, composites theory and additive manufacturing.

Aknowledgements

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